

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE



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In RE Application of:
Applicant: Doyle et al

Examiner: Yasko, Jr. J
Group Art Unit: 3763
Attorney Docket : KJ-100

Serial No.: 09/364,343
Filed: 07/30/99
For: Wound Irrigation and Debriding System

Assistant Commissioner of Patents
Washington, D.C. 20231

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RESPONSE

Dear Sir:

This response is directed to Office Action dated 09/05/00. A petition for extension of time to respond has been filed.

Examiner has rejected claims 1,7,8 under 35 U.S.C. §102 (b) as anticipated by or, in the alternative, under 35 U.S.C. §103 (a) as obvious over Lee, Volckening at al, Van Eck, or Hussey. Applicants respectfully traverse this rejection.

It is clear in the case law that anticipation of a claim under §102 "can be found only if the prior art reference discloses every element of the claim...". Re King (1986, CAFC) 801 Fed 1324, 231 USPQ 136). Anticipation can be found only if "each and every limitation is found either expressly or inherently in a single prior art reference". Celeritas Techs, Ltd. V. Rockwell Int'l Corp. 1998, CAFC) 150 F3d 1354, 47 USPQ 2d 1516, 1522.

On the issue of obviousness, the courts have consistently held that the scope of the prior art is that art which is reasonably pertinent to the particular problem with which the inventor is involved. See, for example, Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F2d 443, 230 USPQ 416 (1986, CAFC). "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art". (*id.*). Further, the inventor is only presumed knowledgeable for prior art in the field of his endeavor that is reasonably pertinent to a particular problem towards which the invention is involved. Union Carbide Corp. v. American Can Co., 724 F2d 1567, 220 USPQ 584, 588 (1984, CAFC). In evaluating obviousness, the claimed invention must be considered

as a whole. Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc., 807 F2d 955, 1 USPQ2d 1196, 1198 (1986 CAFC).

Lee requires a "sleeve-like cover 20 for enclosing tube 16" (col.2, lines 12-13) and is heat-sealed to the dispenser 12 and around the periphery of the end opening of cover 20 where the inner surface of the dispenser mates with the outer surface of the cover. (col.2, lines 25-30).

In the embodiments of Figs. 1,2,3, the distal tip of the tube, which tip is open, is sealed by fitting it into a recession or a protuberance in cover 20 to prevent flow or evaporation of the solution. (col.2, lines 16-20 and 21-24).

When the dispenser is initially used, the seals must be broken, usually by providing a twisting motion. If only a portion of the solution is used, the dispenser is reinserted into its cover for later use. (col.2, lines 33-40).

Applicants suggest that Lee's patent does not include, even substantially or inherently, each and every element of Applicants' invention, nor does it render Applicants' invention obvious.

Applicants' invention does not require a cover nor a heat seal. It does not require a twisting motion to first detach the cover from the dispenser. In Lee, if the twisting or other motion is too sharp, the dispensing opening in the tube could well be damaged and exposed to contamination. In the event, replacing the tube after its first use leaves no seal between the cover and the dispenser and possibly an ineffective seal between the opening and the protuberance or recession in the cover. This, in turn, could expose the solution to possible contamination.

Lee's third embodiment, shown in Fig. 4, describes the use of a stopper 40 to close opening 19 "after each use of the stopper". (col.2, lines 45-50). Applicants suggest that such alternative does not solve the problems associated with the original, initial opening of the dispenser from its cover.

Applicants' invention, on the other hand, is a disposable, one- piece unit that does not require any twisting or breaking of seals to extract the solution chamber from a cover. It does not need a cover, nor sealing such as Lee. It is completely free standing should there be an interruption in the wound irrigation process, and not exposed to contamination. Finally, it can be quickly and efficiently used under emergency situations.

Volckening, et al discloses a container comprising at least two flexible sheets of metal foil or the like sealed together to form a compartment containing the commodity to be dispensed. Within the container is a discharge tube, one end of which is closed by intertwined portions of metal foil to retain the fluent commodity. The discharge tube B also serves to hold the flexible walls of the compartment against external pressure, but allows squeezing the walls to force out the commodity.

Opening the intertwined portions of foil to release the commodity is affected by gripping the two exposed portions between the thumbs and index fingers of the hands of the user and pulling the two portions apart. This opens the cavity and the user may squeeze the container to force out the commodity. It is not explained how the two untied portions are protected from interfering with the dispensed commodity.

Applicants submit that this configuration does not contain each and every element of Applicants' invention and does not teach or anticipate the invention, nor render Applicants' invention obvious. The entire system for dispensing the commodity itself is significantly different. Applicants do not rely on untying the ends of metal foil by hand to open the dispenser nor of retying the ends by hand to close it. Nor is Applicants' invention subject to the real danger of contamination from untying and tying the end portions or preventing interference and thus potential contamination with the dispensed commodity. Applicants submit that such system is inherently subject to possible contamination, inefficiency, slowness, fragility, and not adaptable to an emergency room or similar situation.

Van Eck is a hypodermic syringe which comprises an ampule for storing the medication and a hypodermic needle for injecting the medication into the patient.

The embodiment shown in Figs. 1-5 of Van Eck is a two- piece unit, not the one-piece system invented by Applicant. To use this system, one must remove the tab 15 from the ampule and also peel away the sealing 17 covering the hypodermic needle and then attach the needle to the ampule. (col.3, lines 20-37). In an emergency room or other similar environment in which speed is essential, Van Eck's embodiment takes precious time, can easily be dropped while in the process, under stress, of performing all of the above- described actions, and is open to possible contamination to the needle or the ampule while both are uncovered.

Contrast this embodiment of Van Eck's with that of Applicants' one-piece system which only requires removing the packaging band 12 and protective tip 13, a process which is quick, efficient, and protects against contamination.

Van Eck's embodiment shown in Fig. 6 describes a system where the needle is already attached to the ampule and is covered by assembly 31 which also covers the mouth of the ampule 29. The assembly has a plug which fits over the top of the needle. The sleeve 39 of the assembly extends from the plug over the length of the needle and mouth of the ampule. The assembly is heat- sealed or otherwise bonded to the ampule; (col.4, line 21-44) the needle requires pre-sterilization.(col.col.5, lines 4-5). Here again, this embodiment differs substantially from Applicants' with the inclusion of the bonded cover assembly, which must first be broken from the ampule by pulling or twisting and then stripped from the needle, losing valuable time and subject to possible human clumsiness under emergency conditions.

The other embodiments of Van Eck describe various means of closure of the ampule. Applicants' invention cannot read on or be obvious in view of these embodiments as it is a one-piece system.

Applicants' invention also does not use a hypodermic needle and can therefore be disposed of in any receptacle. Van Eck's system can only be discarded into a Sharp Hazard container at considerable cost to the facility, as noted in Applicants' specifications. Further, unlike Van Eck's ampules which are half-filled (col.5, lines 60-63), Applicants' solution chamber can be totally filled.

Applicants' submit that Van Eck's patent does not contain each and every element of Applicants' invention, either substantially or inherently, nor does it render their invention obvious, and requests that the rejection under §102 (a) and §103 (a) be withdrawn.

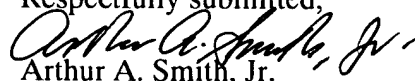
Hussey describes a one- piece enema unit comprising bottle 10, rectal tip 15 with a break- off tab 20 which, in turn consists of a spherical ball 20 mounted on top of the tip so as to completely enclose the circular passage through the tip, in an attempt to prevent any contamination or spillage of the fluid. The ball is removed by twisting it. The tip is coated with a lubricant. A sleeve 30 is slid over the tip and heat- shrunk so as to protect the lubricant on the tip from contamination (col.3, lines 1-26).

Applicants submit that the unit described by Hussey does not anticipate nor does it render obvious Applicants' invention. The object of Hussey is to devise a means of ensuring that the unit is tamper proof and spillage proof and that the lubricant on the tip is safe from contamination prior to use. (col.1, line 55-65).

Applicants' invention is a wound irrigation unit. It does not require lubricating the nozzle and is not intrusive. Applicants solve the problems of preventing contamination, tampering, and spillage by providing a protective tip at the end of the nozzle around which is wrapped a protective band. Applicants' invention thus addresses the needs of a wound irrigation system that is contaminant-free, cannot be tampered with prior to use, and is ready for instant use under emergency conditions. Applicants respectfully suggest that the closure system patented by Hussey, requiring a break-off tab, a twist-off ball, and a heat-shrunk sleeve is so substantially different from Applicants wound irrigation system as not to anticipate under §102 (b), nor to render obviousness under §103 (a).

Examiner also notes art of interest to show disposable dispensers. (Portnoy et al, Klein et al, and Conningham). Applicants do not claim disposability per se as their invention. Disposability is merely one element of the overall invention, which must be viewed in its entirety.

Respectfully submitted,

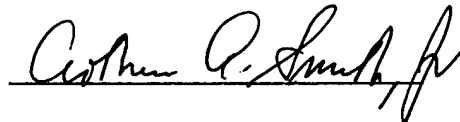

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail No. ET185061941 US in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on March 5, 2001.

A handwritten signature in cursive script, reading "Arthur A. Smith, Jr.", written over a horizontal line.

Arthur A. Smith, Jr.